

MON 87769 × MON 89788 soybean

Soybean with Stearidonic Acid (SDA) and herbicide-tolerance

Key facts



**Bayer Agriculture BV
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Soybean, a key crop

Soybean (*Glycine max*) is a high-protein legume grown mainly as food for humans and livestock. It is one of the highest natural source of dietary fibre (Dhingra *et al.*, 2012). Nine essential amino acids are found in soybeans, which are necessary for human nutrition and are not produced naturally in the body (Tessari *et al.*, 2016). This crop is also used in industrial products including oils, soaps, cosmetics, resins, plastics, inks, solvents, and biodiesel.

The first record of domesticated soybean dates back to the 11th century BC in the eastern half of China where it was grown as food. Soybean was cultivated for the first time in Europe in the early 1700's and in North America in the early 1800's.

In 2021-2022, approximately 349.37 million metric tons of soybean were produced in the world, which represents approximately 130.18 million hectares of soybean harvested globally. Significant areas of production included Brazil, United States (US), Argentina, India and China representing 31.3%, 26.8%, 12.3%, 9.6% and 6.5% of the global soybean hectares, respectively¹.

The European Union (EU) is not a significant soybean producer. In 2021, the soybean area harvested in the EU-27 accounted for approximately 990 thousand hectares². Because of its low production and its high demand, especially for animal consumption, the EU is the world's largest importer of soybean meal². In 2021, the EU-27 imported 18 million metric tons of soybean meal. Brazil, US, Canada and Ukraine are among the largest exporters to the EU³.

What is MON 87769 × MON 89788?

MON 87769 × MON 89788 was obtained by traditional breeding of two independent genetically modified soybean events, MON 87769 and MON 89788. MON 87769 × MON 89788 combines the traits of agronomic interest from the two parental events, *i.e.* production of stearidonic acid (SDA) and tolerance to glyphosate.

MON 87769 × MON 89788 as well as the genetically modified parental soybean events MON 87769 and MON 89788 have been developed by Monsanto Company, now Bayer CropScience LP.

More information on the parental events can be found on the CropLife Europe (CLE) website⁴.

Worldwide plantings and regulatory status of MON 87769 × MON 89788

In 2019, approximately 190.4 million hectares of genetically modified (GM) crops were grown worldwide⁵. In the case of biotech soybean, it continued to be the principal biotech crop in 2019, occupying 91.9 million hectares.

MON 87769 × MON 89788 has received regulatory approval for production in the US. MON 87769 × MON 89788 also received regulatory approvals for food and/or feed imports in multiple countries. Updated information on the status of agricultural genetically modified seeds for agriculture can be found on the CropLife International Biotradestatus database on this website:

<http://www.biotradestatus.com/>

A stringent regulatory system for genetically modified crops in the EU

In the EU, the regulatory system for GM crops comprises several regulations and directives, including Directive 2001/18/EC for deliberate release of genetically modified organisms (GMOs) in the environment, Regulation (EC) No 1829/2003 on GM Food and Feed and Commission Implementing Regulation (EU) No 503/2013.

Directive 2001/18/EC includes procedures for the authorisation of deliberate release into the environment of GMOs, whereas Regulation (EC) No 1829/2003 includes procedures for the authorisation of deliberate release (cultivation and/or import, and processing), in addition to food and feed use, according to the “one door, one key” principle. Commission Implementing Regulation (EU) No 503/2013 includes requirements for applications for authorisation of GM food and feed in accordance with Regulation (EC) No 1829/2003.

A regulation on traceability and labelling of GMOs and products produced from GMOs (Regulation (EC) No 1830/2003) entered into force on 18 April 2004.

Furthermore, a regulation laying down the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material for which an authorisation procedure is pending or the authorisation of which has expired (Commission regulation (EU) No 619/2011) entered into force on 24 June 2011.

Regulatory status of MON 87769 × MON 89788 in the EU

On 30 July 2010, Monsanto Company submitted an application for import, for food and feed use of MON 87769 × MON 89788 soybean as any other soybean (excluding cultivation) under Regulation (EC) No 1829/2003 to the European Food Safety Authority (EFSA) via the Dutch Competent Authority. The application received the reference number EFSA-GMO-NL-2010-85 and was declared valid on 26 November 2010. On 17 September 2015, EFSA adopted an inconclusive opinion as the “GMO Panel could not complete a full assessment on the possible impact of MON 87769 × MON 89788 soybean oil on health and nutrition, because of the lack of data on

¹ USDA (2022) - <https://apps.fas.usda.gov/psdonline/app/index.html#/app/dowloads> (Accessed on 31 May 2022)

² Index mundi (2022) - <https://www.indexmundi.com/agriculture/?commodity=soybean-meal&graph=imports> (Accessed on 31 May 2022)

³ European Commission (2022) - [https://ec.europa.eu/agriculture/market-](https://ec.europa.eu/agriculture/market-observatory/crops/oilseeds-protein-crops/soy-trade_en)

[observatory/crops/oilseeds-protein-crops/soy-trade_en](https://ec.europa.eu/agriculture/market-observatory/crops/oilseeds-protein-crops/soy-trade_en) (Accessed on 31 May 2022)

⁴ Crop Life Europe (2021) - <https://croplifeeurope.eu/product-information/> (Accessed on 31 May 2022)

⁵ ISAAA (2019) - <http://www.isaaa.org/resources/publications/> (Accessed on 31 May 2022).

dietary exposure to refined bleached deodorised (RBD) oil from MON 87769 × MON 89788 soybean”. On 25 April 2019, Bayer provided additional data and on 14 May 2021, the EFSA concluded that “soybean MON 87769 × MON 89788, as described in this application, is as safe as its conventional counterpart and the tested non-GM reference varieties with respect to potential effects on human and animal health and the environment”⁶.

On 16 February 2022, the European Commission (EC) presented the Draft Commission Implementing Decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON 87769 × MON 89788, to the Standing Committee on Plants, Animals, Food and Feed (PAFF) for a vote. After this vote, since no qualified majority was reached, the draft decision was passed to the Appeal Committee (AC) who met for a vote on 5 April 2022, again without reaching a qualified majority. Therefore, the AC forwarded the draft decision to the EC who granted the authorisation on 19 May 2022⁷.

Regulatory status of the parental lines

The EC authorised MON 87769 and MON 89788 foods, food ingredients, and feed containing, consisting of, or produced from these events, or products other than food and feed containing or consisting of these events for the same uses as any other soybean with the exception of cultivation under Regulation (EC) No 1829/2003 on 24 April 2015 (Commission Implementing Decision (EU) 2015/686^{8,9}) and on 28 November 2019 (Commission Implementing Decision (EU) 2019/2083⁹), respectively.

Traceability, labelling, unique identifier

Operators handling or using MON 87769 × MON 89788 and derived foods and feeds in the EU are required to be aware of the legal obligations regarding traceability and labelling of these products, laid down in Regulations (EC) No 1829/2003 and 1830/2003. The unique identifier for this product is MON-87769-7 × MON 89788-1.

In July 2010, MON 87769 × MON 89788 samples of food and feed and control samples were provided to the Joint Research Centre (JRC), acting as the European Union Reference Laboratory (EURL). The EURL considers that the detection methods validated on the parental soybean events, MON 87769 and MON 89788, show a comparable performance when applied to MON 87769 × MON 89788. The detection methods for MON 87769 and MON 89788 had been previously validated by the EURL and are available on the EURL website¹⁰. The validation report for MON 87769 × MON 89788, prepared by the EURL is also available on the same website.

Food, feed and environmental safety of MON 87769 × MON 89788

Food and feed safety

MON 87769 × MON 89788 was obtained by traditional breeding of two independent genetically modified soybean events, MON 87769 and MON 89788. The safety assessment was essentially carried out in two steps:

- Demonstration that the characteristics of the parental lines are maintained in MON 87769 × MON 89788.
- Safety assessment of the combined product, taking into consideration the safety of the parental lines.

The molecular analysis of the DNA inserts present in MON 87769 × MON 89788 confirmed that the insert structures of the parental soybean lines were retained. Also, NcΔ15D, PjΔ6D and CP4 EPSPS protein levels in grain and forage of MON 87769 × MON 89788 were comparable to the levels in the corresponding parental soybean lines.

The conclusions of safety for NcΔ15D, PjΔ6D and CP4 EPSPS, as already demonstrated in the context of MON 87769 and MON 89788, remain applicable when these proteins are produced in combination in MON 87769 × MON 89788. It is unlikely that if interactions between NcΔ15D, PjΔ6D and CP4 EPSPS were to occur, these would raise any safety concerns.

The compositional and nutritional analysis showed that, except for the intended NcΔ15D, PjΔ6D and CP4 EPSPS protein expressions, and the associated intended changes to the fatty acid content, there are no biologically relevant differences in the characteristics of MON 87769 × MON 89788 as compared with its conventional counterpart and that the composition fell within the range of non-GM soybean varieties⁶.

Also, in their scientific opinion, the EFSA concluded that “*that the two-event stack soybean, as described in this application, is as safe as and nutritionally equivalent to its conventional counterpart and the non-GM reference varieties tested*”⁶.

In conclusion, combining MON 87769 and MON 89788 via traditional breeding does not lead to safety concerns, and like the parental lines, MON 87769 and MON 89788 was shown to be as safe and as nutritious as the conventional soybean counterpart.

Further details on the safety of MON 87769 × MON 89788 are available in the EFSA scientific opinions adopted on 17 September 2015¹¹ and 14 April 2021⁶.

⁶ EFSA (2021) [Scientific Opinion on the statement complementing the EFSA Scientific Opinion on application \(EFSA-GMO-NL-2010-85\) for authorisation of food and feed containing, consisting of and produced from genetically modified soybean MON 87769 × MON 89788](#). EFSA Journal 2021;19(5):6589, 18 pp. - Accessed on 31 May 2022

⁷ European Commission (2022) [Commission Implementing Decision \(EU\) 2022/798 of 19 May 2022 authorising the placing on the market of products containing, consisting of or produced from genetically modified soybean MON 87769 × MON 89788 pursuant to Regulation \(EC\) No 1829/2003 of the European Parliament and of the Council](#) - Accessed on 31 May 2022

⁸ Amended by Commission Implementing Decision (EU) 2019/1579 of 18 September 2019

⁹ Amended by Commission Implementing Decision (EU) 2021/184 of 12 February 2021

The application for the renewal of this authorisation is pending EC decision.

¹⁰ EURL - <http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx> - Accessed on 31 May 2022

¹¹ EFSA (2015) [Scientific Opinion on an application \(EFSA-GMO-NL-2010-85\) for the placing on the market of MON 87769 MON 89788 soybean, genetically modified to contain stearidonic acid and be tolerant to glyphosate for food and feed uses, import and](#)

Environmental safety

The environmental safety of MON 87769 × MON 89788 was established based on the following:

- The agronomic and phenotypic analyses confirmed that MON 87769 × MON 89788 does not possess characteristics that would confer a plant pest risk compared to conventional soybean.
- The environmental interaction analyses confirmed that MON 87769 × MON 89788 does not confer any biologically meaningful increased susceptibility or tolerance to specific disease, insect or abiotic stressors.

The likelihood of MON 87769 × MON 89788 would spread into the non-agronomic environment is negligible, since it is not more invasive in natural habitats than conventional soybean. Moreover, the scope of the authorisation covers the import, processing and all uses as any other soybean, but excluding cultivation in the EU, and no deliberate release of the viable plant material in the EU environment is expected, thereby limiting the environmental exposure to accidental spillage only.

Also, in its scientific opinion, the EFSA concluded that *“the two-event stack soybean would not raise safety concerns in the event of accidental release of viable GM soybean seeds into the environment”*¹¹.

MON 87769 × MON 89788, the benefits

MON 87769 × MON 89788 combines the benefits to consumers, farmers and the environment from the two single events, MON 87769 and MON 89788.

Contact point for further information

Since traders may commingle MON 87769 × MON 89788 with other commercial soybean, including authorised GM soybean, Bayer is working together with other members of the plant biotechnology industry within CropLife Europe and trade associations representing the relevant operators in order to implement a harmonised monitoring methodology.

Operators in the food and feed supply chain and/or any other person wishing to report a potential adverse effect associated with the import or use of Bayer soybean products, can therefore refer to the CropLife Europe website at:

<https://croplifeurope.eu/product-information/>

If required, additional comments or questions relative to MON 87769 × MON 89788 can also be addressed at:

<https://www.cropscience.bayer.com/en/support/contact-us>

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[processing under Regulation \(EC\) No 1829/2003 from Monsanto.](#)
[EFSA Journal 2015;13\(10\):4256, 25 pp.](#) - Accessed on 2 June 2022